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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,848	07/24/2006	Ulla Hellstrom	620-438	5041

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,848	HELLSTROM ET AL.	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,4-12,20 and 22* is/are allowed.

6)☒ Claim(s) *13-19* is/are rejected.

7)☒ Claim(s) *2 and 3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 2 and 3 are objected to because of the following informalities: The claims do not end with a period. Appropriate correction is required.

Withdrawn Rejections

The rejection of claims 1-12 and 20-22 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of predicting whether an individual having HBV infection will respond to interferon alpha, does not reasonably provide enablement for a method of predicting whether an individual having HBV infection will respond to interferon other than interferon alpha has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1-22 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of applicants' amendments to the claims.

The rejection of claim 23 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language has been withdrawn in view of applicants' cancellation of the claim.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Neurath et al. (EP 154902A).

The claims are directed to a kit for use in predicting whether an individual having hepatitis B will respond to interferon alpha (IFN α) treatment, the kit comprising; a preS1 peptide consisting of the sequence of residues 94-117 (SEQ ID NO: 1) (claim 13), wherein said peptide is immobilized on a solid support (claim 14) that can be a microtiter plate (claim 15), wherein the kit further comprises a labeled secondary antibody which binds to human antibodies (claim 16), regents for detecting the binding of the labeled secondary antibody (claim 17), wash buffers (claim 18) and sample-handling containers (claim 19).

Neurath et al. discloses a kit for detecting the presence of antibodies to pre-S of hepatitis B Virus in a test sample comprising:

a) a given amount of a peptide containing an amino acid chain corresponding to at least six consecutive amino acids within the pre-S gene coded region of the envelope

of HBV, the peptide being free of an amino acid chain corresponding to the naturally occurring envelope proteins of hepatitis B virus. The peptide is attached to a solid support, e.g., a water insoluble solid support, and

b) labeled antibodies, e.g., radiolabeled or enzyme labeled, to human IgG and/or IgM.

The kit can comprise a set of instructions for effecting an immunoassay, wherein the extent of formation of an immune complex is revealed by said labeled antibodies (see page 18, line 29 to page 19, line 15).

Neurath et al. also teaches preferred peptides of the invention, including SEQ ID NO:1 (see page 31, lines 24-25 and claim 25).

The kit of Neurath et al. is used in a process for the detection of antibodies to proteins coded for by the pre-S region of hepatitis B virus DNA, comprising the following steps:

(a) adsorbing on a solid substrate containing binding sites thereon, e.g., polystyrene beads, a peptide having an amino acid sequence corresponding to at least six consecutive amino acids within the pre-S gene coded region of the HBV envelope,

(b) contacting the substrate from step a with a material to saturate the binding sites thereon,

c) washing the substrate from step b,

d) contacting the substrate from step c with a specimen comprising human sera,

(e) incubating the resultant mass of step d,

(f) washing the resultant mass of step e,

(g) adding radiolabeled antibodies to human IgG or IgM to the resultant mass of step f to form a second resultant mass,

(h) subjecting the second resultant mass of step g to counting in a gamma counter,

(i) subjecting normal sera utilized as a control to steps (a) to (h), and

(j) comparing the counts of steps h and i.

In the above process for the detection of antibodies, ELISA techniques can be substituted for RIA techniques (see page 20, line 14 to page 21, line 13).

Because the kit is used in the assay as described above, the kit would inherently have reagents for detecting the labeled secondary antibody, wash buffers, and sample-handling containers. Because Neurath et al. suggests using ELISA techniques to detect antibodies, Neurath et al. implicitly teaches the use of microtiter plates which are routinely and commonly used in ELISA assays.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Neurath et al. (EP 448126A).

The claims are directed to a kit for use in predicting whether an individual having hepatitis B will respond to interferon alpha (IFN α) treatment, the kit comprising; a preS1 peptide consisting of the sequence of residues 94-117 (SEQ ID NO: 1) (claim 13), wherein said peptide is immobilized on a solid support (claim 14) that can be a microtiter plate (claim 15), wherein the kit further comprises a labeled secondary antibody which binds to human antibodies (claim 16), regents for detecting the binding

of the labeled secondary antibody (claim 17), wash buffers (claim 18) and sample-handling containers (claim 19).

Neurath et al. discloses a kit for detecting the presence of antibodies to pre-S of hepatitis B Virus in a test sample comprising:

a) a given amount of a peptide containing an amino acid chain corresponding to at least six consecutive amino acids within the pre-S gene coded region of the envelope of HBV, the peptide being free of an amino acid chain corresponding to the naturally occurring envelope proteins of hepatitis B virus. The peptide is attached to a solid support, e.g., a water insoluble solid support, and

b) labeled antibodies, e.g., radiolabeled or enzyme labeled, to human IgG and/or IgM.

The kit can comprise a set of instructions for effecting an immunoassay, wherein the extent of formation of an immune complex is revealed by said labeled antibodies (see page 9, lines 9-17).

Neurath et al. also teaches preferred peptides of the invention, including SEQ ID NO:1 (see page 13, lines 30-31).

The kit of Neurath et al. is used in a process for the detection of antibodies to proteins coded for by the pre-S region of hepatitis B virus DNA, comprising the following steps:

(a) adsorbing on a solid substrate containing binding sites thereon, e.g., polystyrene beads, a peptide having an amino acid sequence corresponding to at least six consecutive amino acids within the pre-S gene coded region of the HBV envelope,

(b) contacting the substrate from step a with a material to saturate the binding sites thereon,

c) washing the substrate from step b,

d) contacting the substrate from step c with a specimen comprising human sera,

(e) incubating the resultant mass of step d,

(f) washing the resultant mass of step e,

(g) adding radiolabeled antibodies to human IgG or IgM to the resultant mass of step f to form a second resultant mass,

(h) subjecting the second resultant mass of step g to counting in a gamma counter,

(i) subjecting normal sera utilized as a control to steps (a) to (h), and

(j) comparing the counts of steps h and i.

In the above process for the detection of antibodies, ELISA techniques can be substituted for RIA techniques (see page 9, lines 35-53).

Because the kit is used in the assay as described above, the kit would inherently have reagents for detecting the labeled secondary antibody, wash buffers, and sample-handling containers. Because Neurath et al. suggests using ELISA techniques to detect antibodies, Neurath et al. implicitly teaches the use of microtiter plates which are routinely and commonly used in ELISA assays.

Claims 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Neurath et al. (U.S. Patent No. 4,847,080).

The claims are directed to a kit for use in predicting whether an individual having hepatitis B will respond to interferon alpha (IFN α) treatment, the kit comprising; a preS1 peptide consisting of the sequence of residues 94-117 (SEQ ID NO: 1) (claim 13), wherein said peptide is immobilized on a solid support (claim 14) that can be a microtiter plate (claim 15), wherein the kit further comprises a labeled secondary antibody which binds to human antibodies (claim 16), regents for detecting the binding of the labeled secondary antibody (claim 17), wash buffers (claim 18) and sample-handling containers (claim 19).

Neurath et al. discloses a kit for detecting the presence of antibodies to pre-S of hepatitis B Virus in a test sample comprising:

a) a given amount of a peptide containing an amino acid chain corresponding to at least six consecutive amino acids within the pre-S gene coded region of the envelope of HBV, the peptide being free of an amino acid chain corresponding to the naturally occurring envelope proteins of hepatitis B virus. The peptide is attached to a solid support, e.g., a water insoluble solid support, and

b) labeled antibodies, e.g., radiolabeled or enzyme labeled, to human IgG and/or IgM.

The kit can comprise a set of instructions for effecting an immunoassay, wherein the extent of formation of an immune complex is revealed by said labeled antibodies (see col. 8, lines 27-43).

Neurath et al. also teaches preferred peptides of the invention, including SEQ ID NO:1 (col. 14, lines 8-10 and claim 22).

The kit of Neurath et al. is used in a process for the detection of antibodies to proteins coded for by the pre-S region of hepatitis B virus DNA, comprising the following steps:

(a) adsorbing on a solid substrate containing binding sites thereon, e.g., polystyrene beads, a peptide having an amino acid sequence corresponding to at least six consecutive amino acids within the pre-S gene coded region of the HBV envelope,

(b) contacting the substrate from step a with a material to saturate the binding sites thereon,

c) washing the substrate from step b,

d) contacting the substrate from step c with a specimen comprising human sera,

(e) incubating the resultant mass of step d,

(f) washing the resultant mass of step e,

(g) adding radiolabeled antibodies to human IgG or IgM to the resultant mass of step f to form a second resultant mass,

(h) subjecting the second resultant mass of step g to counting in a gamma counter,

(i) subjecting normal sera utilized as a control to steps (a) to (h), and

(j) comparing the counts of steps h and i.

In the above process for the detection of antibodies, ELISA techniques can be substituted for RIA techniques (col. 9, lines 3-31).

Because the kit is used in the assay as described above, the kit would inherently have reagents for detecting the labeled secondary antibody, wash buffers, and sample-

handling containers. Because Neurath et al. suggests using ELISA techniques to detect antibodies, Neurath et al. implicitly teaches the use of microtiter plates which are routinely and commonly used in ELISA assays.

Allowable Subject Matter

Claims 1, 4-12, 20 and 22 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Stacy B Chen/

Primary Examiner, Art Unit 1648